

Association between average 24-hour diuresis and permanent urine catheter blockage and derived financial consequences in the Central Denmark Region

Breindahl L RN-Continence adviser, Aarhus University Hospital, Urology Department, [Aarhus-Denmark.. lbk@sk.s.aaa.dk](mailto:lbk@sk.s.aaa.dk). Grundal AA-Chief of primary homecare Aarhus. aase@aarhus.dk, Thoft Jensen B-Research Nurse-MPH, Aarhus University Hospital, Urology Department K, Aarhus-Denmark., thoft@c.dk

Background

In a statement from 1994, 3.9% had a permanent catheter in the Danish municipalities[1]. This is equivalent to the prevalence in the countries Denmark is compared with [2]. The prevalence of patients with permanent catheters in the Municipality of Aarhus in 2008 was 0.18 (CI;0,16-0,20) [3]. Permanent catheters can be placed urethrally or suprapubically. Suprapubic catheters are considered superior to urethral catheters concerning frequency of urinary tract infections [4,5]. Catheters are often made of silicone [5,6] and must be changed at least every third month [7].

Permanent catheters are associated with increased morbidity and mortality [2,4,6] and derived health-economic costs. The most frequent complications are bacteraemia, urinary tract infections, encrustations and catheter blockage[5,6,8]. A catheter blockage occurs when the urine cannot pass the lumen in the catheter. This could be due to encrustation. Encrustation is a result of ion components in the urine being crystallised into the living biofilm. The biofilm is a layer of colonised micro-organisms lining the inside of the catheter [9,10]. The urease-producing bacterium *Proteus Mirabilis* is the most frequent cause of this phenomenon [6,9,10,11,12]. The biofilm and its bacteria colonies in the catheter are rarely the same as in the urine collected in a bag [6,12]. This is important in the control, treatment and monitoring strategies of patients with permanent urinary catheters. All types of catheters are vulnerable to this problem and there is no efficient way to control or avoid this problem [2,9,12,13]. More studies indicate that around 50% of all catheter users experience catheter blockage [1,14]. With the current knowledge in this area it is not possible to predict who are "blockers" and who are "non-blockers".

Research shows that the pH value of the urine plays an important role in the encrustation process [6,12,15,16]. The urine salts crystallise differently at different pH values (pH-n). The variation in frequency of catheter encrustations in patients infected with *Proteus Mirabilis* depend on the difference in pH value of the urine (PH-v) and the pH value at the time of encrustation (pH-n)[17,18]. In vitro studies have shown that an increase in pH-n will increase the average time before encrustation and subsequent catheter blockage [19]. The same studies have shown that pH-n can be increased by increasing the 24-hour diuresis. However, clinical experiences are still sparse. In a previous pilot study from 2007 Grundal and Breindahl[20] studied the possible connection between 24-hour diuresis and catheter blockage in citizens with permanent catheters in the Municipality of Aarhus, Denmark. This study showed no significant connection between average 24-hour diuresis and catheter blockage contrary to European in vitro studies[14]. At a cut off point at 1200 ml there was a connection between catheter blockage and 24-hour diuresis below 1200 ml. Due to the size of the study the result can only be interpreted as a tendency. Important sources of error such as lack of stringent registration of diureses and catheter blockage could have biased the result. More clinical studies are thus needed to shed light on a possible connection between 24-hour diuresis and frequency of changing catheters due to *Proteus Mirabilis* as a part of a prevention strategy in patients with permanent catheters.

Aim of the study:

To describe and analyse the connection between average 24-hour diuresis and frequency of catheter change due to incrustation problems among citizens in the Central Denmark Region with permanent catheters and a positive *Proteus Mirabilis* urinary culture.

Hypothesis:

Average 24-hour diureses of 1200 ml or more reduce the frequency of catheter change in citizens with a positive *Proteus Mirabilis* culture.

Average 24-hour diureses of 1200 ml or more reduce health expenditures related to catheter change in citizens with permanent catheters.

Material and method

Study population

Citizens in the Municipality of Aarhus with permanent urethral or suprapubic urinary catheters contacting primary care due to incrustation problems who have had their catheter changed more frequently than every sixth week.

Data

Data are collected by registration schemes distributed to citizens. Patients with a high frequency of catheter change due to incrustation in combination with positive *Proteus Mirabilis* urinary culture are included. 24-hour diureses are observed for five days and the frequency of catheter change is registered retrospectively. Financial data are collected from the Department of Clinical Microbiology, Aarhus University Hospital, Skejby, the Municipality of Aarhus, Municipal Authority 3, and the distributional accounts at the Department of Urology, Aarhus University Hospital, Skejby. All numbers are calculated in 2006 prices.

Inclusion criteria

- 40 persons with permanent catheters in whom catheters are changed more frequently than every six weeks due to incrustation problems.
- Positive *Proteus Mirabilis* culture ($\geq 10^6$)
- All females and males ≥ 18 years of age can participate.

Exclusion criteria

- Citizens who remove catheters themselves.
- Acute disease demanding treatment.
- Medical urinary infection prophylaxis.

Method

Patients are recruited according to above criteria. Following oral and written information, informed consent to participate is obtained. If the patient has a positive *Proteus Mirabilis* culture the patient is taught to register 24-hour diuresis and a manual is handed out. If the patient is not able to make the registrations caring staff is instructed and home visits by the project coordinator and primary care staff are arranged.

The 24-hours urine volume is registered for a period of five consecutive days and nights. Measuring cups for urine collection and a scheme for registration of the urine volume are handed out. The urine bag is emptied in the measuring cup at night time and when getting up in the morning. The volume is registered in the scheme. If it is necessary to empty the bag several times, the same procedure is followed. Persons using catheter valve empty the urine in the measuring cup as needed or at night time and when getting up in the morning. The volume is registered in the scheme by the citizen himself or by the care staff. At the end of the period the scheme is sent to the project coordinator in the prepaid envelope.

Financial data

An average cost estimate of change of permanent catheters is made. The costs are fixed by DAGS rates in 2006 prices.

Statistics

Data will be registered in Epidata and analysed in Stata 9 intercooled®.

Reportings are made in proportions and per cent with 95% confidence intervals (95% CI). Significance testing is made by χ^2 -test at a 5% significance level. Correlation analysis are made by Pearson's test. Subsequently, regression analyses are made with frequency of catheter blockage as dependent variable. Associations are reported with an odds ratio as association targets with 95% CI. P-values $<0,05$ considers to be significant!

The study is only generating hypotheses as there are no previous clinical studies on the subject and it is not possible a priori to measure sample size. The number of participants is thus decided on the basis of financial and practical considerations.

Ethics

Approval

The Helsinki Declaration is followed and the project protocol has been submitted to the Central Denmark Committee on Biomedical Research Ethics and the Danish Data Agency Board for approval. Appendix on participant information is included.

Ethical considerations

The study is explorative hypothesis-generating study. It can provide information on the direction of future studies trying to investigate the reasons for incrustation of permanent catheters.

The examinations will not influence the care and treatment of the participants and the study involves no risk for the participants. The urine volume is measured for five days and nights and it only involves some practical efforts on the part of the participant or care staff. Participation in the project helps finding possible connections between catheter

blockage and Proteus Mirabilis and 24-hour diuresis. In the long term this project can provide improved knowledge about prevention of catheter blockage and possible focus areas to help relieve recurrent problems of catheter blockage, which have major implications on QoL. Personal data are stored and destroyed 15 years after the end of the study. Data on test subjects are protected by law on sensitive personal data and legal rights of patients. Patients are not paid a fee for participating in the study.

After initial contact concerning participating the participant is informed orally and in writing. The participants are informed they have the right to have a lay representative. The participants are given time to give possible consent to participate. All information and data collection are managed by the project coordinators. It is possible to gain access to the project protocol according to applying rules.

Participant information and consent

Enclosed.

Financing

The study will be financed by public and private funds. See appendix.

Publication

The results of the study will be published at relevant congresses and meetings.

Publication right

The publication rights are assigned to Aase Grundal, Lisbeth Breindahl and Bente Thoft Jensen as first author. The counsellor will be co-author.

Reference list

- [1] Zimakoff J, Pontoppidan B, Larsen SO, Stickler DJ. Management of urinary bladder function in Danish hospitals, nursing homes and home care. *J.Hosp.Infect.* 1993 Jul;24(3):183-199.
- [2] Getliffe KA. The characteristics and management of patients with recurrent blockage of long-term urinary catheters. *J.Adv.Nurs.* 1994 Jul;20(1):140-149.
- [3] Charlotte Zanchetta. Økonomi og Myndighedsafdelingen.Magistratens afdeling for sundhed og omsorg. Opgørelse af permanente kateterbærere i Århus Kommune. 2007;1.
- [4] Tenke P, Kovacs B, Bjerklund Johansen TE, Matsumoto T, Tambyah PA, Naber KG. European and Asian guidelines on management and prevention of catheter-associated urinary tract infections. *International Journal of Antimicrobial Agents* 2008 2;31(Supplement 1):68-78.
- [5] Bjerklund Johansen TE, Cek M, Naber K, Strachounski L, Svendsen MV, Tenke P. Prevalence of Hospital-Acquired Urinary Tract Infections in Urology Departments. *European Urology* 2007 4;51(4):1100-1112.
- [6] Jacobsen SM, Stickler DJ, Mobley HLT,Shirliff ME. Complicated Catheter Associated Urinary tract infections due to Escherichia coli and Proteus Mirabilis. *Clin.Microiol.Rev.*2008;21(1):26-59
- [7] Dansk Standard. Styring af infektionshygiejne i sundhedssektoren - del 7: krav til brug af katetre, der efterlades som urinvejsdrænage, Dansk Standard, DS 2451-7, 1. udgave. 2001 2001-08-21;1.

- [8] Sabbuba NA, Mahenthalingam E, Stickler DJ. Molecular Epidemiology of *Proteus mirabilis* Infections of the Catheterized Urinary Tract. *J.Clin.Microbiol.* 2003;41(11):4961-4965.
- [9] Stickler D, Young R, Jones G, Sabbuba N, Morris N. Why are Foley catheters so vulnerable to encrustation and blockage by crystalline bacterial biofilm? *Urol.Res.* 2003 Oct;31(5):306-311.
- [10] Tenke P, Riedl CR, Jones GL, Williams GJ, Stickler D, Nagy E. Bacterial biofilm formation on urologic devices and heparin coating as preventive strategy. *International Journal of Antimicrobial Agents* 2004 3;23(Supplement 1):67-74.
- [11] Tenke P, Kovacs B, Jackel M, Nagy E. The role of biofilm infection in urology. *World J.Urol.* 2006 Feb;24(1):13-20.
- [12] Shaw GL, Choong SK, Fry C. Encrustation of biomaterials in the urinary tract. *Urol.Res.* 2005 Feb;33(1):17-22.
- [13] Stickler DJ, Jones GL. Reduced Susceptibility of *Proteus mirabilis* to triclosan. *Antimicrob.Agents Chemother.* 2008 Mar;52(3):991-994.
- [14] Getliffe K. Managing recurrent urinary catheter encrustation. *Br.J.Community Nurs.* 2002 Nov;7(11):574, 576, 578-80.
- [15] Jones GL, Russell AD, Caliskan Z, Stickler DJ. A Strategy for the Control of Catheter Blockage by Crystalline *Proteus mirabilis* Biofilm Using the Antibacterial Agent Triclosan. *European Urology* 2005 11;48(5):838-845.
- [16] Stickler DJ, Morgan SD. Observations on the development of the crystalline bacterial biofilms that encrust and block foley catheters. *J.Hosp.Infec.*2008Aug; 69(4):350-360
- [17] Mathur S, Suller MT, Stickler DJ, Feneley RC. Prospective study of individuals with long-term urinary catheters colonized with *Proteus* species. *BJU Int.* 2006 Jan;97(1):121-128.
- [18] Mathur S, Suller MTE, Stickler DJ, Feneley RCL. Factors affecting crystal precipitation from urine in individuals with long-term urinary catheters colonized with urease-positive bacterial species. *Urol.Res.* 2006;34(3):173-177.
- [19] Stickler DJ, Morgan DJ. Modulation of crystalline *Proteus Mirabilis* biofilm development on urinary catheters.
- [20] Breindahl L, Grundahl A. sammenhæng mellem døgndiureser og kateterstop. En pilotundersøgelse i Århus Kommune. 2007

Appendix 1

Budget

Directly costs

wage costs

Project group (hours 442) 100.000

Conducting research protocol inclusive literature search (74hours)

Information to participants (hours)

Information meeting to all local primary settings (20 hours)

Conducting program for registration of data (30 hours)

Entry data (30 hours)

Analyse data (74 hours)

Describe data(74hours)

Presentation of data (20-30 hours)

Abstract

Poster

Articel

Other expenditures

60 microbiologi of urine cultures (a 495 Dkr) 29.700

Cups for measuring urine 600

Information material 100 pieces:

Manuals for healthcare providers

Manuals for patients and spouses

Schema

Poster

Total 350

office expenses 1.000

Homevisits at the patients

Information and collecting data by the project group (80*20 km a 3,47 Dkr) 5.552

In total 142.202

Overheads

Overheads administration 3 % of directly cots 4.266

In total to be financed DKR 146.468

Estimated budget 2008 46.500

Estimated budget 2009 100.000

Estimated budget in EURO 19.400